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EXAMINER	
PAULS, JOHN A	

ART UNIT	PAPER NUMBER
3686	

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12/27/2012	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/631,000	BLOMQUIST, MICHAEL L.	
	Examiner	Art Unit	
	JOHN PAULS	3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2012*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-5,7-18,23,24,26 and 28-32* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-5, 7-18, 23-24, 26 and 28-32* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. This action is in reply to the communication filed on 19 November, 2012.

2. Claims 1, 7, 10, 16, 17 and 26 have been amended.

3. Claim 19 has been canceled.

4. Claims 1 – 5, 7 – 18, 23, 24, 26 and 28 - 32 are currently pending and have been examined.

Continued Examination Under 37 CFR 1.114

5. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 November, 2012 has been entered.

Transfer of Application

6. This application has been transferred within the Office as a result of Examiner Koppikar's reassignment to a non-examining unit. Applicant is invited to contact the undersigned to schedule a telephonic interview to discuss and resolve the issues set forth in this Office Action.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1 – 5, 7 – 12, 15 - 18, 23, 26 and 28 - 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eggers et al.: (US 5,713,856 A) and in further view of Comer: (US 3,734,229).

CLAIMS 1 and 5

Eggers as shown discloses a modular patient care system that includes the following limitations:

- *entering a plurality of data items into a database stored in the computer, the plurality of data items forming a set of program data, for controlling operation of a medical pump; assigning at least one data key to the set of program data, the data key identifying the set of program data; batch-down loading the plurality of data items into memory within the pump; controlling operation of the pump based on one or more of the data items;* (see at least Eggers column 10 line 62 to column 11 line 20).

Eggers teaches a modular patient care system that includes a computer into which drug libraries and drug delivery protocols may be entered. The drug libraries and protocols may be downloaded into the patient care system, which includes an infusion pump, for controlling the

pump's operation. The drug libraries and protocols are "keyed" by the drug name/concentration to which it applies. With respect to the following limitations:

- *uploading the plurality of data items* (i.e. *a set of program data) from the pump back to the computer; comparing the data items that were downloaded into the pump to the data items that were uploaded back from the pump; generating an error if the data items that were downloaded into the pump are not identical to the data items that were uploaded back from the pump; and controlling operation of the pump based on one or more of the data items if the data items that were downloaded into the pump are identical to the data items that were uploaded back from the pump.*

While Eggers does not disclose verifying data downloaded to the pump by re-transmitting the data back to the computer for comparison; such re-transmission schemes are notoriously old and well known. For example, Comer teaches a system that verifies that data transmitted to a controlled device is accurate by re-transmitting the data from the controlled device back to the source where it is compared. (see at least Comer column 5 line 27 – 43 and column 5 line 64 to column 6 line 36). Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the a modular patient care system of Eggers so as to have included verifying data by re-transmission techniques, in accordance with the teaching of Comer, in order to insure the accuracy of the transmitted data, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

CLAIM 2

The combination of Eggers/Comer as shown discloses the limitations shown above relative to

Claim 1. Additionally, Eggers discloses the following limitations:

- *entering a plurality of data items into a database includes entering the plurality of data items into a program data record in the database; and assigning at least one data key to the set of program data includes entering the data key into a data key record and linking the data key record to the program data record;* (see at least Eggers column 10 line 62 to column 11 line 20).

Eggers teaches that the drug libraries are stored and selected based on the drug name (i.e. a data key); therefore the drug name and program data are inherently "linked".

CLAIM 3

The combination of Eggers/Comer as shown discloses the limitations shown above relative to Claim 2. Additionally, Eggers discloses the following limitations:

- *entering an identification code selected from the group consisting essentially of a patient I.D., a therapy I.D., and a fluid I.D., wherein the patient I.D. is a code identifying a patient, the therapy I.D. is a code identifying a therapy administered using a medical pump, and the fluid I.D. is a code identifying a fluid that is administered using a medical pump;* (see at least Eggers column 4 line 14 – 19).

CLAIM 32

The combination of Eggers/Comer as shown discloses the limitations shown above relative to Claim 2. Additionally, Eggers discloses the following limitations:

- *the plurality of data items includes at least one data item selected from the group consisting of data items related to delivery schedules, medication doses, and boluses;* (see at least Eggers column 10 line 62 to column 11 line 20).

CLAIM 4

The combination of Eggers/Comer as shown discloses the limitations shown above relative to Claim 3. Additionally, Eggers discloses the following limitations:

- *scanning a bar code with the scanner; and entering the bar code into the computer;* (see at least Eggers column 13 line 20 – 28).
- *wherein the act of assigning at least one data key to the set of program data includes assigning the bar code to the set of program data;* (see at least Eggers column 4 line 11 - 19).

Eggers teaches that a barcode reader may be used to input drug libraries or drug delivery profiles. The barcode provide access to the library or profile and therefore acts as a "key".

CLAIMS 7 and 9

Eggers as shown discloses a modular patient care system that includes the following limitations:

- *memory loaded with a database, the database including a plurality of program data records and a plurality of data key records, each program data record containing a set of program data items for controlling operation of a medical pump, each data key record containing a data key and each data key identifying one of the data program records; a database management system programmed to link a data key to a set of program data and to batch download data to the memory within the medical pump,;* (see at least Eggers column 10 line 62 to column 11 line 20).

Eggers teaches a modular patient care system that includes a computer into which drug libraries and drug delivery protocols may be entered. The drug libraries and protocols may be downloaded into the patient care system, which includes an infusion pump, for controlling the

pump's operation. The drug libraries and protocols are "keyed" by the drug name/concentration to which it applies. With respect to the following limitations:

- *wherein the database management system is further programmed to receive the data downloaded to the medical pump back from the medical pump, compare the data downloaded to the medical pump to the data received back from the pump, and generate an error message if the data downloaded to the pump does not match the data received back from the pump.*

While Eggers does not disclose verifying data downloaded to the pump by re-transmitting the data back to the computer for comparison; such re-transmission schemes are notoriously old and well known. For example, Comer teaches a system that verifies that data transmitted to a controlled device is accurate by re-transmitting the data from the controlled device back to the source where it is compared. (see at least Comer column 5 line 27 – 43 and column 5 line 64 to column 6 line 36). Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the a modular patient care system of Eggers so as to have included verifying data by re-transmission techniques, in accordance with the teaching of Comer, in order to insure the accuracy of the transmitted data, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

CLAIM 8

The combination of Eggers/Comer as shown discloses the limitations shown above relative to Claim 7. Additionally, Eggers discloses the following limitations:

- *a scanner in data communication with the database management system;* (see at least

Eggers column 13 line 20 – 28);

- *the database management system being further programmed to receive a code scanned by the scanner, save the code in a data key record, and link the code to a set of program data, the code being a data key;* (see at least Eggers column 4 line 11 - 19).

Eggers teaches that a barcode reader may be used to input drug libraries or drug delivery profiles. The barcode provide access to the library or profile and therefore acts as a "key".

CLAIM 10

Eggers as shown discloses a modular patient care system that includes the following limitations:

- *memory loaded with a database, the database including a plurality of program data records and a plurality of data key records, each program data record containing a set of program data items for controlling operation of a medical pump, each data key record containing a data key and each data key identifying one of the data program records; a data output configured for data communication with a programmable medical pump;* (see at least Eggers column 10 line 62 to column 11 line 20);
- *a processor in electrical communication with the memory and the data output, the processor configured to retrieve a set of program data from the database and batch download the set of program data to the memory within the medical pump;* (see at least Eggers column 10 line 62 to column 11 line 20).

Eggers teaches a modular patient care system that includes a computer into which drug libraries and drug delivery protocols may be entered. The drug libraries and protocols may be downloaded into the patient care system, which includes an infusion pump, for controlling the pump's operation. The drug libraries and protocols are "keyed" by the drug name/concentration

to which it applies. With respect to the following limitations:

- *the processor further configured to receive back from the pump an upload of the program data that was downloaded to the pump, compare the program data received back from the pump with the program data downloaded to the pump and generate an error message if the program data received back from the pump does not match the program data that was downloaded to the pump.*

While Eggers does not disclose verifying data downloaded to the pump by re-transmitting the data back to the computer for comparison; such re-transmission schemes are notoriously old and well known. For example, Comer teaches a system that verifies that data transmitted to a controlled device is accurate by re-transmitting the data from the controlled device back to the source where it is compared. (see at least Comer column 5 line 27 – 43 and column 5 line 64 to column 6 line 36). Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the a modular patient care system of Eggers so as to have included verifying data by re-transmission techniques, in accordance with the teaching of Comer, in order to insure the accuracy of the transmitted data, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

CLAIMS 11 and 12

The combination of Eggers/Comer as shown discloses the limitations shown above relative to Claim 10. Additionally, Eggers discloses the following limitations:

- *a serial communication cable connected to the data output;* (see at least Eggers column 10 line 46 – 47);

- *a medical pump in data communication with the data output;* see at least Eggers column 10 line 46 to column 11 line 20).

CLAIM 15

The combination of Eggers/Comer as shown discloses the limitations shown above relative to Claim 10. Additionally, Eggers discloses the following limitations:

- *the processor is programmed to generate a user interface, the user interface including a plurality of graphical fields for program data;* (see at least Eggers column 3 line 10 – 24).

CLAIM 23

The combination of Eggers/Comer as shown discloses the limitations shown above relative to Claim 10. Additionally, Eggers discloses the following limitations:

- *the data key record includes a field, the field for storing a therapy name;* (see at least Eggers column 10 line 62 – 67).

CLAIM 16

Eggers as shown discloses a modular patient care system that includes the following limitations:

- *selecting a set of program data, for controlling operation of a medical pump; and batch downloading the set of program data to the memory within the medical pump wherein the set of program data is downloaded to the medical pump without intervening action by a user after a first data item of the set of program data is downloaded to the computer, wherein an information management system is loaded on the computer and the information management system includes a database storing a plurality of data keys and a plurality of program data sets and the act of batch downloading the set of program*

data includes downloading the set of program data from the computer to the medical pump; (see at least Eggers column 10 line 62 to column 11 line 20).

Eggers teaches a modular patient care system that includes a computer into which drug libraries and drug delivery protocols may be entered. The drug libraries and protocols may be automatically downloaded into the patient care system, which includes an infusion pump, for controlling the pump's operation. The drug libraries and protocols are "keyed" by the drug name/concentration to which it applies. With respect to the following limitations:

- *uploading the set of program data from the medical pump to the computer after it is downloaded to the medical pump; comparing the set of program data that was downloaded to the medical pump to the set of program data that was uploaded from the medical pump; and generating an error if the set of program data that was downloaded from the medical pump is not identical to the program data that was uploaded from the medical pump.*

While Eggers does not disclose verifying data downloaded to the pump by re-transmitting the data back to the computer for comparison; such re-transmission schemes are notoriously old and well known. For example, Comer teaches a system that verifies that data transmitted to a controlled device is accurate by re-transmitting the data from the controlled device back to the source where it is compared. (see at least Comer column 5 line 27 – 43 and column 5 line 64 to column 6 line 36). Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the a modular patient care system of Eggers so as to have included verifying data by re-transmission techniques, in accordance with the teaching of Comer, in order to insure the accuracy of the transmitted data, since so doing could be performed readily

and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

CLAIM 17

The combination of Eggers/Comer as shown discloses the limitations shown above relative to Claim 16. Additionally, Eggers discloses the following limitations:

- *entering a data key into the information management system; referencing the data key to a program data set; and retrieving the referenced program data set from the database;* (see at least Eggers column 16 line 34 – 42).

CLAIM 18

The combination of Eggers/Comer as shown discloses the limitations shown above relative to Claim 17. Additionally, Eggers discloses the following limitations:

- *the act of entering a data key includes scanning a bar code;* (see at least Eggers column 4 line 11 - 19).

Eggers teaches that a barcode reader may be used to input drug libraries or drug delivery profiles. The barcode provide access to the library or profile and therefore acts as a "key".

CLAIM 26

Eggers as shown discloses a modular patient care system that includes the following limitations:

- *a housing; a pump mechanism positioned within the housing;* (see at least Eggers Figure 1);
- *memory positioned within the housing and configured to store a plurality, of data items forming a set of program data for controlling operation of a medical pump; a first program module programmed to receive a batch download of the plurality of data items*

from a computer, second program module programmed to control operation of the pump mechanism according to the batch downloaded plurality of data items; (see at least Eggers column 10 line 62 to column 11 line 20).

Eggers teaches a modular patient care system that includes a computer into which drug libraries and drug delivery protocols may be entered. The drug libraries and protocols may be automatically downloaded into the patient care system, which includes an infusion pump, for controlling the pump's operation. The drug libraries and protocols are "keyed" by the drug name/concentration to which it applies. With respect to the following limitations:

- *the first program module further configured to upload the plurality of data items back to the computer and receive an error message from the computer if the data items downloaded from the computer are not identical to the data items uploaded back to the computer.*

While Eggers does not disclose verifying data downloaded to the pump by re-transmitting the data back to the computer for comparison; such re-transmission schemes are notoriously old and well known. For example, Comer teaches a system that verifies that data transmitted to a controlled device is accurate by re-transmitting the data from the controlled device back to the source where it is compared. (see at least Comer column 5 line 27 – 43 and column 5 line 64 to column 6 line 36). Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the a modular patient care system of Eggers so as to have included verifying data by re-transmission techniques, in accordance with the teaching of Comer, in order to insure the accuracy of the transmitted data, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk

of unexpected results.

CLAIMS 28 - 31

The combination of Eggers/Comer as shown discloses the limitations shown above relative to Claim 16. Additionally, Eggers discloses the following limitations:

- *the program data identifies a therapy name;* (see at least Eggers column 10 line 62 – 67);
- *the program data includes a data key;* (see at least Eggers column 10 line 62 – 67);
- *the first and second program module include code executable by a processor;* (see at least Eggers column 6 line 59 – 62 and column 11 line 46 – 63);
- *the first and second program modules comprise program code;* (see at least Eggers column 6 line 59 – 62 and column 11 line 46 – 63).

10. Claim 13, 14 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eggers et al.: (US 5,713,856 A) and in further view of Comer: (US 3,734,229) and in further view of Coutre et al.: (US 5,153,827 A).

CLAIMS 13, 14 and 24

The combination of Eggers/Comer as shown discloses the limitations shown above relative to Claim 23. Eggers/Comer may not specifically disclose the following limitations; however, Coutre does:

- *each data key record includes fields for a patient I.D., a therapy I.D., and a fluid I.D.;* (see at least Coutre column 5 line 26 to column 6 line 63);
- *each data key record includes first and second fields, the first field for storing an identification code and the second field from storing a name in prose;* (see at least Coutre column 2 line 14 – 16);

- *the data key record includes an additional field, the additional field for storing a therapy I.D.;* (see at least Coutre column 2 line 14 – 16);

Coutre teaches an infusion management system that includes a database having a plurality of fields including patient ID, drug name and drug ID. Examiner equates drug with therapy. Coutre also stored the carrier solution for the infusion (fluid ID). Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the a modular patient care system of Eggers/Comer so as to have included various fields in a database for infusion orders, in accordance with the teaching of Coutre, in order to provide a complete record of the infusion, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results. Examiner notes that any field in a relational database may be considered a "key".

Response to Arguments

Applicant's arguments, filed 19 November, 2012, with respect to Claim 19 have been fully considered and are persuasive. The Non-Final Office Action of 17 May, 2012 has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Comer.

CONCLUSION

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **John A. Pauls** whose telephone number is **(571) 270-5557.** The Examiner can normally be reached on Monday to Friday 7:30 to 5:00. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **JERRY O'CONNOR** can be reached at **571.272.6787**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see *http://portal.uspto.gov/external/portal/pair*. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197**. Official replies to this Office action may now be submitted electronically by registered users of the EFS-Web system. Information on EFS-Web tools is available on the Internet at: *http://www.uspto.gov/patents/process/file/efs/guidance/index.jsp*. An EFS-Web Quick-Start Guide is available at: *http://www.uspto.gov/ebc/portal/efs/quick-start.pdf*.

Alternatively, official replies to this Office action may still be submitted by any ***one*** of fax, mail, or hand delivery. **Faxed replies should be directed to the central fax at (571) 273-8300**. Mailed replies should be addressed to "Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450." Hand delivered replies should be delivered to the "Customer Service Window, Randolph Building, 401 Dulany Street, Alexandria, VA 22314."

/JOHN A. PAULS/
Examiner, Art Unit 3686
Date: 19 December, 2012